(3) A brief summary of the available data on health effects;

(4) An estimate of when the Secretary anticipates the issuance of a proposal;

(5) An invitation to interested parties to provide relevant information;

(6) A statement that persons wishing to provide OSHA with their own study should complete it within 30 days after the anticipated proposal date; and

(7) A statement of the procedural requirements that must be met before substantial new issues or substantial new evidence will be considered in the proceeding pursuant to §1990.145.

(b) Where the Secretary determines to discontinue a feasibility study, the Secretary should publish, within 30 days, a notice in the FEDERAL REGISTER so indicating.

§1990.142 Initiation of a rulemaking.

Where the Secretary decides to regulate a potential occupational carcinogen, the Secretary shall initiate a rulemaking proceeding in accordance with one of the following procedures, as appropriate.

(a) *Notice of proposed rulemakings (section 6(b) of the Act)*—(1) *General.* The Secretary may issue a notice of proposed rulemaking in the FEDERAL REGISTER, pursuant to section 6(b) of the Act and part 1911 of this chapter. The notice shall provide for no more than a sixty (60) day comment period, and may provide for a hearing, which shall be scheduled for no later than one hundred (100) days after publication of the Notice of Proposed Rulemaking. The commencement of the hearing may be postponed once, for no more than thirty (30) days, for good cause shown.

(2) *Provisions of the proposed standard for Category I Potential Carcinogens.* Whenever the Secretary issues a notice of proposed rulemaking to regulate a substance as a Category I Potential Carcinogen:

(i) The proposed standard shall contain at least provisions for scope and application, definitions, notification of use, a permissible exposure limit, monitoring, regulated areas, methods of compliance including the development of a compliance plan, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, hygiene facilities, medical surveillance, employee information and training, signs and labels, recordkeeping, and employee observation of monitoring as set forth in §1990.151, unless the Secretary explains why any or all such provisions are not appropriate;

(ii) The model standard set forth in §1990.151 shall be used as a guideline, and

(iii) The permissible exposure limit shall be achieved primarily through engineering and work practice controls except that if a suitable substitute is available for one or more uses no occupational exposure shall be permitted for those uses.

(3) *Provisions of the proposed standard for Category II Potential Carcinogens.* Whenever the Secretary issues a Notice of Proposed Rulemaking to regulate a substance as a Category II Potential Carcinogen:

(i) The proposed standard shall contain at least provisions for scope and application, definitions, notification of use, monitoring, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, medical surveillance, employee information and training, recordkeeping and employee observation of monitoring as set forth in §1990.151, unless the Secretary explains why any or all such provisions are not appropriate; and

(ii) The model standard set forth in §1990.151 shall be used as a guideline; and

(iii) Worker exposure to Category II Potential Carcinogens will be reduced as appropriate and consistent with the statutory requirements on a case-by-case basis in the individual rulemaking proceedings. Any permissible exposure level so established shall be met primarily through engineering and work practice controls.

(b) *Emergency temporary standards (section 6(c) of the Act)*—(1) *General.* The Secretary may issue an Emergency Temporary Standard (ETS) for a Category I Potential Carcinogen in accordance with section 6(c) of the Act.

(2) *Provisions of the ETS.* (i) The ETS shall contain at least provisions for scope and application, definitions, notification of use, a permissible exposure limit, monitoring, methods of

compliance including the development of a compliance plan, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, medical surveillance, employee information and training, signs and labels, recordkeeping and employee observation of monitoring, unless the Secretary explains why any or all such provisions are not appropriate.

(ii) The model standard set forth in §1990.152 shall be used as a guideline.

(iii) The permissible exposure limit shall be achieved through any practicable combination of engineering controls, work practice controls and respiratory protection.

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

§1990.143 General provisions for the use of human and animal data.

Human and animal data which are scientifically evaluated to be positive evidence for carcinogenicity including the following policies shall be uniformly relied upon for the identification of potential occupational carcinogens. Arguments challenging the following provisions or their application to specific substances will be considered in individual rulemaking proceedings only if the evidence presented in support of the arguments meets the criteria for consideration specified in §1990.144 or §1990.145.

(a) *Positive human studies.* Positive results obtained in one or more human epidemiologic studies will be used to establish the qualitative inference of carcinogenic hazards to workers.

(b) *Positive animal studies.* Positive results obtained in one or more experimental studies conducted in one or more mammalian species will be used to establish the qualitative inference of carcinogenic hazard to workers. Arguments that positive results obtained in mammalian species should not be relied upon will be considered only if evidence is presented which meets the criteria for consideration specified in §1990.144(c) or 1990.144(f).

(c) *Non-positive human studies.* Positive results in human or mammalian studies generally will be used for the qualitative identification of potential occupational carcinogens, even where non-positive results from human studies exist. Such non-positive results will be considered by the Secretary only if the studies or results meet the criteria set forth in §1990.144(a).

(d) *Non-positive animal studies.* Positive results in one or more mammalian studies will be used for the qualitative identification of potential occupational carcinogens, even where non-positive studies exist in other mammalian species. Where non-positive and positive results exist in studies in the same species, the non-positive results will be evaluated.

(e) *Spontaneous tumors.* Positive results in human or mammalian studies for the induction or acceleration of induction of tumors of a type which occurs ''spontaneously'' in unexposed individuals will be used for the qualitative identification of potential occupational carcinogens.

(f) *Routes of exposure.* (1) Positive results in studies in which mammals are exposed via the oral, respiratory or dermal routes will be used for the qualitative identification of potential occupational carcinogens, whether tumors are induced at the site of application or distant sites.

(2) Positive results in studies in which mammals are exposed via any route of exposure and in which tumors are induced at sites distant from the site of administration will be used for the qualitative identification of potential occupational carcinogens.

(3)(i) Positive results in mammalian studies in which tumors are induced only at the site of administration, in which a substance or mixture of substances is administered by routes other than oral, respiratory or dermal, will be used as ''concordant'' evidence that a substance is a potential occupational carcinogen.

(ii) Arguments that such studies should not be relied upon will be considered only if evidence which meets the criteria set forth in §1990.144(b) is provided.

(g) *Use of high doses in animal testing.* Positive results for carcinogenicity obtained in mammals exposed to high doses of a substance will be used to establish the qualitative inference of carcinogenic hazard to workers. Arguments that such studies should not be relied upon will be considered only if